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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/771,277 | 01/26/2001 | Jose A. Olivares | 4250.2.6 | 7977 |

21552 7590 05/02/2003

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| ART UNIT | PAPER NUMBER |
|---|---|
| 1753 | 7 |

DATE MAILED: 05/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

mk 7

| Office Action Summary | Application No. | Applicant(s) |
|---|---|---|
| | 9/771,277 | Jose A. Olivares et al. |
| | Examiner | Group Art Unit |
| | J. STARSIAK | 1753 |

*—Th MAILING DATE of this communication appears on th cover sheet beneath th correspondence address—*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Statu**

☒ Responsive to communication(s) filed on 26 January 2001.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

**Disposition of Claims**

☒ Claim(s) 1-50 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-26 and 28-50 is/are rejected.

☒ Claim(s) 27 is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement

**Application Papers**

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

**Pri rity under 35 U.S.C. § 119 (a)-(d)**

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).

☐ All ☐ Some* ☐ None of the:

☐ Certified copies of the priority documents have been received.

☐ Certified copies of the priority documents have been received in Application No. _____.

☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a))

*Certified copies not received: _____.

**Attachment(s)**

☒ Information Disclosure Statem nt(s), PTO-1449, Paper No(s). 2,4,5

☐ Int rview Summary, PTO-413

☒ Notice of Ref rence(s) Cited, PTO-892

☐ Notice of Inf rmal Patent Application, PTO-152

☐ Notice of Draftsperson's Pat nt Drawing Revi w, PTO-948

☐ Oth r _____

**Office Action Summary**

## DETAILED ACTION

### *Claim Rejections - 35 U.S.C. § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-18, 34-37, and 49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 recites, " wherein the electrolyte buffer comprises tris-boric acid EDTA, potassium tartare, tris-acetate EDTA, a gel sieving material, and a surface deactivating agent. Claim 34 recites, "wherein the electrolyte buffer comprises tris-boric acid EDTA (TBE), potassium tartrate, tris-acetate EDTA (TAE), a gel sieving material, and a surface deactivating agent". From the written description of the invention and from the fact that TBE and TAE perform the same function it appears that this is an improper Markush group. In other words, it appears that the applicant is attempting to claim an electrolyte buffer with one or more of the above ingredients. Claims 17, 18, and 35-37 are rejected because they depend on either claim 16 or 34.

Claim 49 contains the trademark/trade name Teflon AF. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte*

*Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. a trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a particular polytetrafluoroethylene and, accordingly, the identification/description is indefinite.

***Claim Rejections - 35 U.S.C. § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> a person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 11, 12, 17-19, 24-26, 29-31, 34-36, and 38-40 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Beale & Sudmeier.

Beale & Sundmeier teaches [ABSTRACT]: " a laser-induced (LIF) detector using opillumination and confocal optical detection geometry is disclosed. The LIF detector is designed to scan the entire length of the separation capillary.". Beale & Sudmeier teaches [page 3368,

right-hand column]: " a Spellman (Planeview, NY) CZE1000R high-voltage power supply was used to generate the electric field across the capillary....The separation potential was always kept below 15 kV...". Regarding the recitation of buffer chambers in claim 2 see Figure 1 of Beale & Sudmeier. Beale & Sudmeier teaches [page 3367, right-hand column]: "the confocal laser fluorescence detector is shown schematically in figure 1. The output radiation (488 nm) from an air cooled Omnichrome Model 532-5BS argon ion laser head passes through a neutral density filter....Using the tube current control on the laser head and various combinations of OD 1.0 and 0.3 neutral density filters, the power transmitted to the capillary can be controlled over a 0.6-25 mW range. The incident beam is....focused into the capillary by a Zeiss 0.42 N.A. 32X Plan Achromat long working distance infinite conjugate microscope objective....The emission signal is focused by a fused silica focusing lens...through a 200 $\mu$m pinhole....and a long pass edge filter (515 nm, Omega Optical)....The photon signal is converted to a current by a Hamamatsu (Bridgewater, NJ) IB28 photomultiplier tube. The current is converted to a voltage, amplified, and filtered by a Stradford Applied Research Systems low-noise SR750 current amplifier. Data are collected through a 12-bit A/D board....and are stored on an IBM PC clone using software written in-house. The capillary, 25-100 $\mu$m i.d. ...". Beale & Sudmeier teaches [page 3370, left-hand column]: " These concepts are illustrated in Figure 4, in which FITC-labeled insulin, myoglobin, lentil lectin, and bovine serum albumin are separated by size in a 6% T linear acrylamide gel.". Beale & Sudmeier teaches [page 3368, left-hand column]: " With the current

stage design, 19 cm of a 26 cm long capillary can be scanned.". In rejecting 16-18 and 34-36 the examiner considers claims 16-18 and 34-36 to be Markush groups.

Claims 1, 3-6, and 15 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Shartle et al.

Shartle et al. teaches [col. 3, lines 17-24]: " The above objects have been achieved in a cartridge containing short capillary tube segments suspended by a planar structure. The capillary tube ends are located adjacent to electrodes formed on the support. When liquid is placed in a gap between the electrode and one of the capillary tube segment is filled by capillary action.". Shartle et al. teaches [col. 5, lines 39-45]: " Electrodes 16 and 18 are connected to an external voltage supply when cartridge 11 is placed in the electrophoresis instrument. In IEF, after separation is complete, capillary tube 14 is scanned by the instrument....Optical detection of fluorescently labeled components labeled components is used in the preferred embodiment.". Shartle et al. teaches [col. 6, line 63 to col. 7, line 32]: " With reference to FIG. 7, an electrophoresis instrument 100 optically scanning a horizontally disposed cartridge 11 is shown. a strongly emitting light source, such as light emitting diode or laser 123 is used to generate a beam. LED 123 has an output power of about 50 milliwatts and a wavelength band which will excite fluorescence in the fluorescent labeling material...The beam is intercepted by a focusing lens 127 which directs the beam through a slit aperture and barrier 129. Light emerging from the slit is divergent and is intercepted by a collimating lens 131. The beam is then directed onto a reflecting surface 133 which is part of a dichroic mirror 135. Dichronic mirror 135 is chosen to selectively

reflect light at the wavelength emitted by light source 123 while transmitting light at the wavelengths emitted by the fluorescent label. The reflected beam is directed toward focusing lens 137. Light passing through the focusing lens carries an image of slit 129 which is directed onto capillary 14. Then image slit 129 can be scanned along the longitudinal axis of capillary 14 by moving separation cartridge relative to the lens. Fluorescent light emitted by a label, and some reflected light from the capillary , travel in the retrobeam to focusing lens 137....From there, the retrobeam is directed to reflecting surface 133 which is part of dichroic mirror 135. Light reflected from the capillary is reflected toward the light source 123 while fluorescent light passed through. The fluorescent light is them directed by a mirror 141 through a filter 143 which rejects any light other than the desired wavelength from the fluorescent label. Light transmitted through the filter is directed toward focusing lens 145. From there the beam is directed to a light detector, such as photomultiplier tube 147 with a slit located at the image plane of the separation medium.".

### *Claim Rejections - 35 U.S.C. § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) a patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 15, 33, and 41-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beale & Sudmeier in view of Shartle et al.

Beale & Sudmeier discloses all the particulars recited in the above claims (see 102 rejection above) except that Beale & Sudmeier discloses a single capillary device and the claims recite a multicapillary device. Shartle et al. discloses a device which is similar to Beale & Sudmeier that has both single capillary embodiments and multicapillary embodiments. It would be obvious toone of ordinary skill in the art at the time of the invention provide the device of Beale & Sudmeier with additional capillaries to increase throughput.

Claims 1-22, 24- 26, and 29-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanning et al. in view of Beale & Sudmeier.

Hanning et al.. teaches [ABSTRACT]: " a new laser-ffluorescence detector for capillary electrophoresis (CE) is described. The detector is based on transverse illumination and collection of the emitted fluorescent light via total internal reflection along the separation capillary. The

capillary is coated with a low refractive index fluoropolymer and serves as a liquid core waveguide (LCW). The emitted light is detected end-on with a CCD camera at the capillary exit....Full four-color DNA sequencing is also demonstrated.... The concept should be highly suitable for capillary array detection.". Hanning et al. teaches [page 3424, left-hand column]: "The separation capillary is externally coated with a polymer (Teflon AF, Du Pont, Wilmington, DE) with a lower refractive index (RI) than the separation medium.". Hanning et al. teaches [page 3425, left hand column]: " The laser was operated at 30 mW.". Hanning et al. teaches [page 3425, left-hand column]: "In this way, the 10-90% intensity width of the laser beam in the axial direction at the capillary was estimated to be 25$\mu$m.". Hanning et al. teaches [page 3425, left-hand column]: " In the gel electrophoresis experiments the capillary was filled with a viscous 7.0 % (w/v) solution of linear poly(dimethylacrylamide) in a 1× TBE (0.1 M tris, 0.1 M borate, 2 mM EDTA), 7M urea buffer". Hanning et al. teaches [page 3424, right-hand column and page 3425, left-hand column]: The emitted fluorescent light was guided ~50 mm to the end of the capillary. The end of the capillary was placed in a liquid-filled chamber. The opposite wall of which was made of planar glass plate, at the focal point of a 27-mm-focal width *f*/0.9 aspheric condenser lens....The primary light was absorbed by one or more glass filters.... Finally, the capillary end was imaged by a 50-mm camera objective....onto a thermoelectrically cooled CCD camera....The collected images were stored and evaluated by means of WinView software....on an IBM-compatible PC. Hanning et al. teaches [page 3425, left-hand column]: " The length of the gel-filled capillary from the injection end to the illumination zone was ~300 mm.". Hanning et al

teaches [page 3425, left hand column]: " The sample was injected at 4 kV for 20 s and electrophoresed at 5 kV.". The only significant difference between the claims and Hanning et al. is that the light source in Hanning et al. is stationary with respect to the capillary and the claims recite the light source scans the capillary along the longitudinal axis of the capillary. Beale & Sudmeier teaches scanning the light source along the longitudinal axis of the capillary has advantages over a stationary light source. Specifically Beale & Sudmeier teaches [page 3367, left-hand column]: "The capability to monitor the progress of the separation process or to dynamically alter the length of the separation bed by scanning the entire capillary offers several advantages over conventional instrumentation. Separation time can be optimized since the duration of the run need only be long enough to resolve the components of interest. Thus, sample throughput will be increased as the solutes do not need to migrate through the entire length of the separation bed.". It would have been obvious to one of ordinary skill in the art at the time of the invention to add means for scanning the light source to the device of Hanning et al. to increase throughput.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hanning et al. in view of Beale & Sudmeier as applied to claim 19 above, and further in view of Li et al.

The device of Hanning et al is illustrated only schematically. Li et al discloses a liquid core waveguide detector in detail. In Li et al. (see Fig. 1) the emitted light passes from the end of the capillary through a fiber optic to the photodiode. The fiber optic allows emitted light to pass out of the cell while forming part of the cell wall (no liquid can flow out of the cell). Also, the use of

a fiber optic allows flexibility of the location of photodetecting elements of a liquid core wavelength detector, i.e. the photodetecting elements do not need to be aligned on the longitudinal axis of the capillary and more of the light exiting the end of the capillary would reach the CCD camera. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the device of Hanning et al. with a fibre optic because of the reasons recited above.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Beale & Sudmeier in view of Kim et al..

In Beale & Sudmeier an interference filter and an edge filter are used to prevent any light except light emitted by the fluorescent label from reaching the photomultiplier tube. The use of narrow bandpass filter to preform the same function is well-known in the laser-induced fluorescence detection art, i.e. Li et al. is one of many examples. Specifically, Li et al. teaches [page 938, left-hand column]: "Band-pass filters 10 nm in width, centered at 540, 560, 580, and 610 nm ... selectively transmit the fluorescence generated from C, A, G, and T fragments to a photomultiplier tube (PMT) detector, respectively. It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute a narrow bandpass filter for the combination of the interference filter and the edge filter of Beale & Sudmeier because they perform the same function.

***Allowable Subject Matter***

Claim 27 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art does not explicitly teach or fairly suggest a device for separating and detecting particles comprising: a capillary having a first end and a second end, the capillary filled with a buffer solution; a first reservoir in fluid communication with the first end of the capillary, the first reservoir configured to contain buffer solution; a second reservoir configured to contain buffer solution; an electrical source for applying a voltage across the capillary, the voltage causing a fluorescently labeled particle positioned within the capillary to travel from a first location within the capillary to a second location within the capillary; an excitation source for directing an excitation beam onto the capillary, such that when a fluorescently labeled particle is positioned within the capillary, the fluorescently labeled particle emits light after excitation with the excitation beam, the excitation source capable of exciting fluorscently labeled particles at more than one position along the capillary; a light detector positioned to collect fluorescent light emitted from the excited fluorescently labeled particle located within the capillary, wherein the light detector comprises low-level light detection electronics and *a high band pass filter for filtering light with a wavelength greater than about 500 nm and a notch filter.*

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Starsiak Jr. whose telephone number is (703) 308-1797. The examiner can normally be reached on Monday to Wednesday from 8:00 AM to 3:30 PM and on Thursday and Friday from 8:00 AM to 12:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM Nguyen, can be reached on (703) 308-3322. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

NAM NGUYEN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700

John S. Starsiak Jr.

29 April 2003